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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,354	12/31/2003	Gregory Waimong Chan	5618P3473	1158

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EXAMINER	
KOHARSKI, CHRISTOPHER	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,354	CHAN ET AL.	
	Examiner	Art Unit	
	Christopher D. Koharski	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) *13-16,29-32,47-50,59-62,88 and 91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,17,18,34-46,51-58,63-87,89,90 and 92-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/13/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed on 1/26/2005 in which Applicant elected species A (Figures 1-10, 16-23) subspecies i, (figure 11) regarding all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03) because no election of eligible claims was made. The claims 13-16, 29-32, 47-50, 59-62 are not readable on the elected invention because they are drawn to a dual balloon device and different embodiments thereof (Figures 29, 30). The claims 88 and 91 are not readable on the elected invention because they are drawn to a non-elected subspecies of needle, i.e. claim 88 (Figure 13) and claim 91 (Figure 14).

Therefore claims 13-16, 29-32, 47-50, 59-62, 88 and 91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and subspecies, there being no allowable generic or linking claim.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 5/20/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Specification

The abstract of the disclosure is objected to because the abstract exceeds the 150 word maximum. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Apparatus and method for a percutaneous needle catheter for controlled injection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 7-8, 11-12, 17-19, 24, 27-28, 33-38, 42-43, 45-46, 51-55, 57-58, 63, 65, 67-81, 85-87, 89-90, and 92-96 are rejected under 35 U.S.C 102(e) as being anticipated by Chow et al. (6,692,466). Chow et al. discloses a drug delivery catheter with retractable needle.

Regarding claims 1-3, 8, 17-19, 24, Chow et al. discloses an expandable body, multiple delivery cannulas, needle disposed in the cannulas, and a stop disposed in the lumen (Figure 4A). The stop comprising a sleeve coupled to the needle having a smaller diameter than the cannula (Figure 4B). The needle cannulas are attached to a hub present on the main body of the catheter (Figure 4A).

Regarding claim 7, Chow et al. discloses a ribbon present in the lumen that modifies the shape of the lumen (Figure 2A).

Regarding claims 11-12, 27-28, 42-43, 45-46, 57-58, 67-71, Chow et al. discloses a needle and hub system that has several different configurations and has a variable angle (Figure 3A-C).

Regarding claims 33-38, Chow et al. discloses an expandable body, multiple delivery cannulas, needle disposed in the cannulas, and a stop disposed in the lumen (Figure 4A). The stop comprising a sleeve coupled to the needle having a smaller diameter than the cannula (Figure 4B). The needle cannulas are attached to a hub present on the main body of the catheter (Figure 4A).

Regarding claims 51-55, Chow et al. discloses an expandable body, multiple delivery cannulas, needle disposed in the cannulas, and a stop disposed in the lumen (Figure 4A). The stop comprising a sleeve coupled to the needle having a smaller diameter than the cannula (Figure 4B). The needle cannulas are attached to a hub present on the main body of the catheter (Figure 4A).

Regarding claim 63 and 65, Chow et al. discloses a first and second cannula in fluid connection with a lumen (Figure 4A) used to penetrate a patients vascular system.

Regarding claims 72-81, Chow et al. discloses an expandable body, multiple delivery cannulas, needle disposed in the cannulas, and a stop disposed in the lumen (Figure 4A). The stop comprising a sleeve coupled to the needle having a smaller diameter than the cannula (Figure 4B). The first are second track of different diameters are present proximal and distal to the needle stop, and are attached to an inflation balloon. The needle cannulas are attached to a hub present on the main body of the catheter (Figure 4A).

Regarding claims 85-87, 89-90, Chow et al. discloses an expandable body with at least one delivery cannula (Figure 1A) with a defined travel path. (Figure 2B). Wherein the needle has a proximal and distal portion coupled to each other (46 and 88) with different outside diameters. This transition point between two sections defines a step (Figure 4B).

Regarding claims 92-96, Chow et al. discloses a device, which is inherently capable of performing the task of being positioned in the body and expanding the balloon member and delivering a treatment agent by advancing a needle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6, 9-10, 20-23, 25-26, 44, 56, 82-83 are rejected under 35 U.S.C 103(a) as being unpatentable over Chow et al. in view of Epstein et al. (6,835,193). Chow et

al. meets the claim limitations as described above but does not include a second stop in the lumen configuration.

However, Epstein et al. teaches a device for controlled injections. Regarding claims 4-6, 20-22, Epstein et al. teaches a needle cannula system with multiple sleeves to stop the needle (both proximal and distal) and the partial sleeve changing the cross sectional shape (Figure 3).

Regarding claims 9-10, 25-26, 44, 56, 82-83 Epstein et al. teaches a second protuberance that limits the total movement of the needle and provides an orientation within the lumen.

Regarding claim 23, Chow et al. discloses a ribbon located in the lumen on the needle cannula (Figure 2A).

At the time of the invention, it would have been obvious to use the needle stop system of Epstein et al. with the needle stop system of Chow et al. because the addition of the second stop provides more precise control over the needle puncture depth. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Epstein et al.

Claim Rejections - 35 USC § 103

Claims 39-41 and 84 are rejected under 35 U.S.C 103(a) as being unpatentable over Chow et al. Chow et al. discloses the claimed invention but does not disclose expressly the distance between the cannula and sheath ring, balloon adhered by adhesive made of cyanacrylate, needle composed of super elastic alloy. It would have

been an obvious matter of design choice to a person of ordinary skill in the art to modify the system of Chow et al. with the materials and dimensions as claimed by Applicant, because Applicant has not disclosed that the materials, adhesive bonding or distance provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a seem-less or bonded design as taught by Chow et al., because it provides a one-piece design for easier construction and more biocompatibility compared to cyanoacrylate adhesive, use of super elastic alloys (Chow et al. discloses a ribbon member made of various elastic materials) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Chow et al.

Therefore, it would have been an obvious matter of design choice to modify Chow et al. to obtain the invention as specified in the claims.

Claim Rejections - 35 USC § 103

Claims 64 and 66 are rejected under 35 U.S.C 103(a) as being unpatentable over Chow et al. in view of Jacobson et al. (6,302,870). Chow et al. meets the claim limitations as described above but does not include the use of nickel-titanium alloy.

However, Jacobson et al. teaches an apparatus for injection into the walls of patient vessels. Regarding claims 64 and 66 Jacobson et al. teaches the use of nickel-titanium alloys and other composites to achieve appropriate strength to accomplish the insertion task (col 3).

At the time of the invention, it would have been obvious to use construction materials of Jacobsen et al. with the system of Chow et al. because the addition of increased strength of materials provides the user with increased penetration and ease of use through the patient's body. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Jacobsen et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on Monday through Friday 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

[Date] 3/6/06

Christopher Koharski
Examiner
Art Unit 3763

[illegible]
SUPERVISORY PATENT EXAMINER
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